Claims

1. A crystalline polymorph Form A of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 5.19 (s), 4.70 (vs), 4.22 (s), 4.00 (s), 3.56 (s), wherein (vs) stands for very strong intensity; (s) stands for strong intensity.

2. A crystalline polymorph Form A of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 5.56 (m), 5.19 (s), 5.00 (m), 4.95 (m), 4.70 (vs), 4.22 (s), 4.00 (s), 3.56 (s), 3.40 (m); wherein (vs) stands for very strong intensity; (s) stands for strong intensity; (m) stands for medium intensity.

3. A crystalline polymorph Form A of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 10.7 (w), 9.6 (w), 7.6 (w), 6.9 (w), 5.56 (m), 5.36 (w), 5.19 (s), 5.00 (m), 4.95 (m), 4.81 (w), 4.70 (vs), 4.59 (w), 4.22 (s), 4.00 (s), 3.91 (w), 3.81 (w), 3.72 (w), 3.56 (s), 3.40 (m), 3.09 (w), 2.83 (w); wherein (vs) stands for very strong intensity; (s) stands for strong intensity; (m) stands for medium intensity; (w) stands for weak intensity.

4. A crystalline polymorph Form A of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate having an X-ray powder diffraction pattern substantially as depicted in Figure 1.

5. A crystalline polymorph Form B of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 10.4 (vs), 5.45 (s), 4.95 (s), 4.71 (s); wherein (vs) stands for very strong intensity; (s) stands for strong intensity.

6. A crystalline polymorph Form B of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 10.4 (vs), 5.89 (m), 5.45 (s), 5.35 (m), 4.95 (s), 4.71 (s), 4.45 (m), 4.36 (m), 3.97 (m), 3.92 (m), 3.89 (m), 3.76 (m), 3.70 (m); wherein (vs) stands for very strong intensity; (s) stands for strong intensity; (m) stands for medium intensity.

7. A crystalline polymorph Form B of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate which exhibits a characteristic X-ray powder diffraction pattern with characteristic peaks expressed in d-values (Å) at 10.4 (vs), 5.89 (m), 5.45 (s), 5.35 (m), 5.18 (w), 4.95 (s), 4.71 (s), 4.45 (m), 4.36 (m), 4.23 (w), 4.18 (w), 3.97 (m), 3.92 (m), 3.89 (m), 3.76 (m), 3.70 (m), 3.50 (w), 3.45 (w), 2.72 (w); wherein (vs) stands for very strong intensity; (s) stands for strong intensity; (m) stands for medium intensity; (w) stands for weak intensity

8. A crystalline polymorph Form B of N,N-dimethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1H-indole-3-ethanamine benzoate having an X-ray powder diffraction pattern substantially as depicted in Figure 2.

9. A process for the preparation of a crystalline polymorph according to any of the claims 1 to 4, in which a solution of Rizatriptan benzoate is cooled and the solution is in an organic solvent, or in a mixture of organic solvents, or in a mixture of an organic solvent with a non-solvent selected from hydrocarbons and ethers or water.

10. A process according to claim 9 in which the organic solvent is selected from an alcohol, a ketone, an acetate.

11. A process according to claim 10 in which the organic solvent is methanol, 1-butanol, 1-octanol, acetone, methyl isobutyl ketone or ethyl acetate.

12. A process according to claim 9 in which the solution is in a mixture of an organic solvent with a non-solvent and the non-solvent is selected from C_5-C_8alkanes, diethylether, ethyl-

butyl ether, ethyl-propyl ether, dipropylether, propyl-butyl ether, dibutylether, tetrahydrofuran, dioxan and mixtures thereof.

13. A process according to claim 12 in which the mixture of organic solvents is a mixture of an acetate and a C_5-C_8alkane.

14. A process according to any of claim 9 to 13 in which the solution is cooled from a temperature of about 20° to 100°C down to about –20°C to 10°C.

15. A process according to claim 14 in which the solution is cooled from a temperature of about 50° to 80°C down to about 0°C to 5°C.

16. A process for the preparation of a crystalline polymorph according to any of the claims 1 to 4, in which a solution of Rizatriptan benzoate in water or in a mixture of water and an organic solvent is evaporated to dryness.

17. A process according to claim 16 in which the solution of Rizatriptan benzoate is in a mixture of water and an organic solvent and the organic solvent is an alcohol.

18. A process according to claim 17 in which the organic solvent is 2-propanol or 1-butanol.

19. A process according to claim 16 in which the solution of Rizatriptan benzoate is in a mixture of water and an organic solvent and the amount of water in the mixture is ranging from 1 to 90 volume%.

20. A process according to claim 19 in which the amount of water in the mixture is ranging from 10 to 30 volume%.

21. A process for the preparation of a crystalline polymorph according to any of the claims 1 to 4, in which an organic non-solvent is added to a solution of Rizatriptan benzoate in a mixture of an organic solvent and water.

22. A process according to claim 21 in which the organic solvent is an alcohol, an ether or a ketone.

23. A process acoording to claim 22 in which the organic solvent is 2-propanol, acetone or tetrahydrofuran.

24. A process for the preparation of a crystalline polymorph according to any of claims 5 to 8, in which Rizatriptan benzoate is obtained by fast crystallization.

25. A process for the preparation of a crystalline polymorph according to any of claims 5 to 8, in which a solution of Rizatriptan benzoate in an alcohol, or in a mixture of an alcoholic and another organic solvent, is added to a non-solvent.

26. A process for the preparation of a crystalline polymorph according to any of the claims 5 to 8, in which a non-solvent is added to a solution of Rizatriptan benzoate in an alcohol or in a mixture of an alcohol with another organic solvent.

27. A process according to claim 25 and 26 in which the solution of Rizatriptan benzoate is in methanol or in a mixture of methanol and ethyl acetate.

28. A process according to any of claim 25 to 27 in which the non-solvent is an alkane.

29. A process according to claim 28 in which the non-solvent is hexane or heptane.

30. A process for the preparation of a crystalline polymorph according to any of the claims 5 to 8, in which a solution of Rizatriptan benzoate in an alcohol is evaporated to dryness.

31. A process according to claim 30 in which the alcohol is 2-propanol or 1-butanol.

32. A process according to any of the claims 9 to 31, wherein seeding is carried out with crystals of the desired crystalline polymorph.

33. A process according to any of the claims 9 to 32 in which the solution of Rizatriptan benzoate is prepared in situ.

34. A process according to claim33 in which the solution of Rizatriptan benzoate is prepared upon reaction of rizatriptan free base with benzoic acid.

35. A pharmaceutical composition comprising an effective amount of a crystalline polymorphic form according to any of claims 1 to 8 and a pharmaceutically acceptable carrier.

36. The composition according to claim 35, wherein said composition comprises an effective amount of a crystalline polymorphic form A.

37. The composition according to claim 35, wherein said composition comprises for each an effective amount of a crystalline polymorphic form B.

38. The composition according to claim 35, wherein said composition comprises for each part by weight of a crystalline polymorphic form A 0.001 to 100 parts by weight of a crystalline polymorphic form B.

39. The composition according to claim 38, wherein said composition comprises for each part by weight of a crystalline polymorphic form A 0.01 to 10 parts by weight of a crystalline polymorphic form B.

40. The composition according to claim 39, wherein said composition comprises for each part by weight of a crystalline polymorphic form A 0.05 to 2 parts by weight of a crystalline polymorphic form B.

41. Use of a pharmaceutical composition according to any of claims 35 to 40 for the manufacturing of a drug for the treatment and/or prevention of migraine.

42. Use of a pharmaceutical composition according to any of claims 35 to 40 for the manufacturing of a medicament for the treatment and/or prevention of clinical conditions for which a selective antagonist of 5-$HT_{1B/1D}$- like receptors is indicated.

43. A method for the treatment and/or prevention of clinical conditions for which a selective antagonist of 5-$HT_{1B/1D}$- like receptors is indicated, comprising administering to a patient in need of such treatment an effective amount of the pharmaceutical composition according to any of claims 35 to 40.

44. A method for the treatment and for prevention of migraine, comprising administering to a patient in need of such treatment an effective amount of the pharmaceutical composition according to any of claims 35 to 40.